IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO PLAINTIFFS: **Carolyn Lewis (2:12-cv-04301)** **Judy Brown (2:12-cv-07314)**	

PRETRIAL ORDER #_____
AGREED ORDER AND STIPULATION REGARDING
PATHOLOGY PROTOCOL FOR PRESERVATION AND TESTING OF EXPLANTS AND TISSUE SAMPLES TAKEN FROM PLAINTIFFS AND HANDLING OF PLAINTIFFS' PATHOLOGY SLIDES IN BELLWETHER GROUP 1 CASES

Counsel for the parties having consented hereto,

IT IS on this ____ day of _________, 2013, ORDERED that:

1. To the extent that explanted mesh or removed pelvic floor tissue (the "Materials") exist for any Bellwether Group 1 Cases specifically referenced herein above, which are set for trial January 14, 2014 (herein after "Bellwether Group 1 Cases"), unless the Materials have already been obtained, such Bellwether Plaintiff will obtain the Materials from the medical facilities currently in possession of the Materials, and will maintain the Materials in an appropriate manner that preserves them for examination, testing and use by both parties. Plaintiffs will notify Defendants when the materials are requested, and shall notify Defendants within seven (7) business days of Plaintiffs obtaining the Materials. The notification shall confirm the type and number of materials obtained, the facility from which the materials were received and the date of the procedure from which the Materials were

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obtained. If the date of the procedure is unknown, Plaintiffs take all reasonable steps to obtain the date of the procedure and to provide Defendants with such information immediately upon receipt. The parties agree that Plaintiffs and Defendants shall document the chain of custody for all Materials using the form attached as Exhibit A. A copy of the chain of custody shall be provided to the other party upon request.

2. To the extent that Materials have already been requested and obtained by Bellwether Group 1 Plaintiffs, within ten (10) days of this Order, agree to provide to Defendants the type and number of materials obtained, the name of the facility from which the materials were received and the date of the procedure from which the Materials were obtained. If the date of the procedure is unknown, Plaintiffs shall take all reasonable steps to obtain the date of the procedure and to provide Defendants with such information as soon as practicable upon receipt. Plaintiffs will also provide chain of custody information for such Materials that are already in possession of Plaintiffs or Plaintiffs' representative.

3. Plaintiffs in the Bellwether Group 1 Cases agree to preserve at least one-half of the Materials in the form received from the medical facility for use by Defendants as they see fit and to photograph the Materials prior to dividing the Materials in half.

a. In the event that any of the Materials are less than 120mg in mass of a representative sample of mesh and surrounding tissue (herein after "Small Sample"), this shall be considered too small to be divided equally among the parties. In the event of a Small Sample, the parties agree to meet and confer and attempt to arrive at a mutually agreeable protocol as to that specific explanted mesh or tissue sample. Neither party will perform any review, analysis, or testing on the Small Sample or alter the Small Sample in any way prior to reaching a mutually agreeable protocol. In the event no agreement can be reached, the parties will seek the Court's guidance.

b. If in the course of dividing the Materials to preserve at least one-half for use by Defendants, it becomes impossible to provide Defendants with Materials that can be used in the same manner that Plaintiffs are able to use their half of Materials, Plaintiffs will immediately notify Defendants. The parties agree to meet and confer and attempt to arrive at a mutually agreeable protocol as to the Materials. Neither party will perform any review, analysis, or testing on the Materials or alter the Materials in any way prior to reaching a mutually agreeable protocol. In the even that no agreement can be reached, the parties will seek the Court's guidance.

c. Paragraphs 3a and 3b shall only apply if the amount of the Materials is such that it cannot be divided in a manner that would permit analysis of a representative sample of mesh and surrounding tissue by both parties, and shall not operate to restrict Plaintiffs' utilization of the Materials under any other circumstances not stated within this Order.

4. Plaintiffs in the Group 1 Bellwether Cases agree to provide Defendants with any slides obtained from pathology preserved (the "Slides") within seven (7) business days after Plaintiffs' experts have reviewed the Slides. Plaintiffs will maintain the Slides in an appropriate manner that preserves them for examination, testing and use by both parties. To the extent Plaintiffs request additional slides be cut from the pathology block for any given procedure for use by Plaintiffs' experts to stain as they require, Plaintiffs in the Group 1 Bellwether Cases agree to ensure duplicate stained slides are created for use by Defendants. To the extent Defendants require additional slides be cut from the pathology block for any given procedure, Defendants will make such request to Ethicon MDL Plaintiffs' counsel Ben Anderson, Jeff Kuntz and/or such other MDL Plaintiffs' counsel that Messrs. Anderson and Kuntz shall designate. Plaintiffs' counsel shall make such request of the facility maintaining the pathology block and request duplicate stained slides for both parties with each party to bear its own costs of such recut and duplication. The parties agree that Plaintiffs will provide Defendants all slides (originals and/or re-cuts) reviewed by Plaintiffs' experts within seven (7) business days of Plaintiffs' experts' review and analysis of the slides and that Defendants will do the same with regard to slides reviewed by Defendants' experts.

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5. This order specifically authorizes and directs any institution in possession of any Materials for a Bellwether Case to provide the Materials to Plaintiffs' counsel when requested, assuming Healthcare Insurance Portability and Accountability Act requirements are otherwise satisfied.

6. Nothing herein shall be construed to limit or constrain the ability of healthcare providers to do what is necessary for the care and treatment of a Plaintiff.

The Court hereby accepts the stipulation of the parties. The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327 and it shall apply to the Bellwether Group 1 cases set for trial on January 14, 2014, *Carolyn Lewis, et al. v. Johnson & Johnson, et al.,(2:12-cv-04301), Judy Brown, et al. v. Ethicon, Inc., et al., (2:12-cv-07314).* In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: ______________, 2013

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JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

APPROVED:

/s/Bryan F. Aylstock

/s/Tom P. Cartmell

/s/D. Renee Baggett

ATTORNEYS FOR PLAINTIFFS

/s/Christy D. Jones

/s/David Thomas

ATTORNEYS FOR ETHICON, INC.
AND JOHNSON & JOHNSON

PATHOLOGY CHAIN OF CUSTODY

Material Originating from ______________________________________
Regarding:

____

Received and/or transferred as indicated, ________________________________ described as follows:

SLIDES/EXPLANTS

1. [Identify each specimen by date, type, appearance and any identifying number. If a pathology slide, identify original or recut and stained or unstained]

FROM: [identify sender by name and address]

____

SIGNATURE

____

DATE

TO: [identify receiving party by name and address

____

SIGNATURE

____

DATE

FROM: [identify sender by name and address

____

SIGNATURE

____

DATE

TO: [identify receiving party by name and address

____

SIGNATURE

____

DATE